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BY CM/ECF AND HAND DELIVERY

The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

Re: *Pfizer Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*,
C.A. No. 17-158 (LPS) (Consolidated)

Dear Chief Judge Stark:

We represent plaintiffs in the above-referenced litigation and write in response to the June 28, 2019 letter of counsel for defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, "Zydus") regarding the parties' dispute as to whether plaintiffs should be required to (i) further respond to defendants' Interrogatory No. 3; and (ii) provide a witness to testify with respect to defendants' Rule 30(b)(6) topics 18 and 23-30.

Plaintiffs have already disclosed the particular secondary considerations that they contend are evidence of non-obviousness, they have identified, by their production numbers, documents reflecting facts supporting each of those secondary considerations, and they have produced two Rule 30(b)(6) witnesses to testify regarding facts underlying their commercial success argument. Moreover, the reports of the experts who will be testifying at trial in support of Pfizer's secondary considerations positions are to be served on August 22, 2019, and Zydus will have an opportunity to provide responsive reports and to depose plaintiffs' experts. Contrary to Zydus's suggestion, it will most certainly not lack "fair notice" of plaintiffs' positions on secondary considerations. Hence, Zydus would have plaintiffs undertake a wholly unnecessary exercise. Zydus's application is without merit and should be denied.

In response to Zydus's Interrogatory No. 3, plaintiffs informed Zydus that they contend that the non-obviousness of the RE'783 patent-in-suit is supported by the secondary considerations of commercial success, industry praise, long felt but unresolved need, failure of others and industry skepticism. Plaintiffs explained that the commercial success, industry praise, and long-felt but unresolved need met by their Xeljanz® and Xeljanz XR® products are

attributable to the compound 3-{4-Methyl-3-[methyl-(7H-pyrrolo [2, 3-d] pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile which is covered by the claims of the RE'783 patent. Plaintiffs further stated that there was industry skepticism with respect to their compound and that competitors had failed to develop a product with comparable efficacy and safety.

Plaintiffs' interrogatory response also identified documents evidencing the secondary considerations on which they plan to rely. The documents supporting commercial success include P & L statements, yearly operating plans and attached spreadsheets, IQVIA data (physician prescribing data, formerly "IMS data"), and articles discussing the market success of Xeljanz post-launch. In addition, plaintiffs listed publications, staff reports and presentations, article summaries, and the candidate alert notice for CP-690,550 (the Pfizer designation for the active ingredient in Xeljanz before it was named tofacitinib) which refer to the long-felt but unresolved need satisfied by Xeljanz. With respect to the failure of others, plaintiffs identified publications, staff reports, and the candidate alert notice for CP-690,550 which note that plaintiffs' competitors developed and were developing immunosuppressive products with side effects that limited their general acceptance or that lacked demonstrated efficacy. Plaintiffs' cited evidence of industry skepticism included articles and summaries of articles which state that rheumatologists had doubts about whether they would prescribe tofacitinib, if it was approved. Finally, as evidence of industry praise, plaintiffs pointed to articles and summaries of articles discussing the significant clinical efficacy of Xeljanz.

By contrast, in *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, C.A. No. 16-905-JFB-CJB, 2018 WL 5292546 (D. Del. Oct. 24, 2018), which Zydus cites, prior to the close of discovery the patentee did not specify which secondary considerations it planned to rely on and identified only five documents which supported just two secondary considerations. In *United States ex rel. Landis*, 317 F.R.D. 592, 593 (D.D.C. 2016), the responding party had included in its interrogatory responses the virtually meaningless statement that "[i]nformation responsive to this request may also be located in previously-produced documents, including as set forth in Attachment A," which listed "over two hundred deposition transcripts and . . . hundreds of other documents produced by the [inquiring party] in discovery."

The bottom line here is that Zydus has had plaintiffs' interrogatory response, including the list categorizing the supporting documents for more than two months, yet they fail to make clear in their letter what information is lacking and what purpose would be served by further requiring plaintiffs to create a narrative describing the contents of the documents. Accordingly, the Court should deny Zydus's application with respect to plaintiffs' response to Interrogatory No. 3.

In asking that plaintiffs be required to produce one or more Rule 30(b)(6) witnesses regarding secondary considerations, Zydus fails to mention that plaintiffs have already produced as Rule 30(b)(6) witnesses Jeffrey Lotz, Vice President of Marketing for Xeljanz, and Joseph Hoban, Finance Director, to testify regarding the potential market for Xeljanz (Topic 19), sales and costs of marketing Xeljanz (Topics 20 and 21) and marketing materials for Xeljanz (Topic 22). In asking that plaintiffs additionally be required to provide Rule 30(b)(6) witnesses to testify on the secondary considerations topics of: commercial success (Topic 18), long felt but unmet need (19), industry praise (24), unexpected results (not asserted by plaintiffs) (25), failure

of others (26), copying (not asserted by plaintiffs) (27), industry skepticism (28), acquiescence (not asserted) (29), "any purported objective indicia of non-obviousness related to methods for treating rheumatoid arthritis, psoriatic arthritis, and/or ulcerative colitis with tofacitinib" (30), Zydus would have plaintiffs provide a Rule 30(b)(6) witness to testify on plaintiffs' contentions regarding secondary considerations.

Indeed, Zydus's letter makes clear that it seeks to require a fact witness to testify regarding plaintiffs' contentions. Zydus's insistence that "it is seeking testimony on *the facts underlying* Pfizer's asserted secondary considerations" (D.I. 130 at 3) ignores that "inserting [] the word 'facts' doesn't make [a deposition topic] less of an effort to get at what is essentially the legal position of the party." *Pharmacia & Upjohn Co. v. Sicor, Inc.*, C.A. No. 04-833-KAJ, at 36 (D. Del. Oct. 11, 2005) (Ex. 1). And Zydus's attempt at re-articulating its deposition topics reveals that what it seeks are contentions: "[W]hat in the laundry list of documents is the alleged 'praise' on which Pfizer will rely?" (D.I. 130 at 3) is a re-wording of "What does Pfizer contend is the industry praise?" and "What in the documents is the particular 'need' related to the asserted patent claims, and how 'long felt' was it?" (*id.*) is really just "What does Pfizer contend is the long-felt need?" However, the Courts in this District do not permit Rule 30(b)(6) depositions regarding contentions. *See Axiohm IPS, Inc. v. Epson Am., Inc.*, C.A. No. 00-420-SLR, Tr. at 4 (D. Del. Mar. 28, 2001) (Ex. 2) ("[W]e don't do contention depositions in this district."); *Purdue Pharma L.P. v. Intellipharmaceutics Int'l Inc.*, C.A. No. 17-392-RGA, D.I. 105 at 2 (D. Del. Apr. 16, 2018) (Ex. 3) ("These are contention deposition topics, and are therefore not permitted."). A layperson should not be required to conduct a legal analysis and articulate plaintiffs' legal contentions regarding the non-obviousness of the subject matter claimed in the patents-in-suit in response to deposition questions. *See Tiegel Manu Co. v. Globe-Union, Inc.*, C.A. No. 84-483-WKS, Tr. at 14 (D. Del. Oct. 5, 1984) (Ex. 4) (denying contention deposition request and explaining that "not even a lawyer should be required to formulate trial strategy and contentions in immediate response to questions on deposition").

This District's position with respect to contention depositions has been applied to depositions concerning contentions as to secondary considerations. *See Medicis Pharma. Corp. v. Actavis Mid Atlantic LLC*, C.A. No. 11-409-LPS-CJB, D.I. No. 242, Tr. at 43-45 (D. Del. Sept. 28, 2012) (Ex. 5) (denying request to depose 30(b)(6) witness on secondary considerations, explaining that "plaintiffs . . . have identified a clear view of the Court here that so-called contention depositions are not favored"). Zydus received notice of the secondary considerations on which plaintiffs intend to rely and the factual bases underlying plaintiffs' contentions. Zydus will have ample opportunity to further explore plaintiffs' contentions during expert discovery.

Accordingly, Zydus's request that plaintiffs be required to provide a witness to testify on Rule 30(b)(6) Deposition Topics 18 and 23-30 should likewise be denied.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

cc: Clerk of Court (Via Hand Delivery)
All Counsel of Record (Via Electronic Mail)